K091586

JUL 23 2009

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow
Date Prepared:	May 26, 2009

B. Device Name: Vascu-PICC® and Midline Catheters, Single, Double and Triple Lumen

Common Name:	Catheter, Intravascular, Therapeutic, Long-Term
Classification Name:	Long Term Intravascular Catheter (80 LJS)
C.F.R. Section:	880.5970
Class:	II

C. Predicate Devices:

K003682 Medcomp, Z-Cath PICC
K001901 Bard Access, Poly-Q-Cath® Midline
K043502 Bard Access, Poly Per-Q-Cath® Triple Lumen PICC Catheter
K051991 Bard Access, Poly-Q-Cath PICC

D. Device Description:

The Vascu-PICC® and Midline Catheters are designed for peripheral vein catheterization. The lumen is an open-ended design comprised of a soft radiopaque polyurethane material with barium sulfate for radiopacity. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration.

The catheters are available in a range of French sizes in single, double and triple lumen. The outside diameter of the lumen has a reverse taper increasing gradually near the hub to aid in kink resistance and to provide a mechanical obstruction to bleeding from the venotomy. The lumen has depth marks every centimeter and numerical marks every 5th centimeter and are available in 20cm for Midline placement and a trimmable 60cm for PICC's.

The Vascu-PICC® and Midline Catheters product line is packaged sterile with the necessary accessories to facilitate catheter insertion.

E. Intended Use:

The Peripherally Inserted Central Vein Access catheters are designed for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For central venous pressure monitoring (CVP), it is recommended that catheter lumen of 20 gauge or larger be used.

The Midline catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (See Contraindications). For blood therapy it is recommended that a 4French or larger catheter be used.

F. Comparison to Predicate Devices:

The Vascu-PICC® and Midline Catheters are substantially equivalent to the predicate devices in terms of intended use, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

The differences between the Vascu-PICC® and Midline Catheters and the predicate Z-Cath device are material change/ formulation, modified design and expansion of product line with additional French sizes and the addition of a triple lumen and midline design.

Indications have been expanded to match the predicate devices.

G. Bench / Performance Data:

The following in-vitro testing was performed on the Vascu-PICC® and Midline Catheters to assure reliable design and performance in accordance with ISO standards.

- Air Leakage
- Liquid Leakage
- Elongation
- Tensile
- Gravity Flow Rate
- Priming Volume
- Aging
- Chemical Testing
- Stress Testing

H. Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993.

I. Technological characteristics:

The principles of operation are the same as the predicate devices. There are no new design changes that could affect the safety or effectiveness of the device.

J. Conclusion:

The proposed devices meet the performance criteria of design verification as specified by ISO standards and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed devices are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jean Callow
Regulatory Specialist
Medcomp
1499 Delp Drive
Harleysville, Pennsylvania 19438

JUL 23 2009

Re: K091586
Trade/Device Name: Vascu-PICC® and Midline Catheters
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: May 29, 2009
Received: July 02, 2009

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christopher D. Nolan for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___ Vascu-PICC® and Midline catheters _____

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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